**The VA Medical Advisory Panel of the Pharmacy Benefits Management Services is comprised of PBM clinical pharmacy specialists and practicing internist and specialist VA physicians from across the country.*

Lacosamide Oral Tablet (Vimpat)

Criteria for Use

March 2016

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.**

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or http://vaww.pbm.va.gov for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive lacosamide.*

☐ Diagnosis of Primarily Generalized seizure types
☐ Use for the treatment of neuropathic pain

Inclusion Criteria *The answers to one of the following must be fulfilled in order to meet criteria.*

- Documented diagnosis of partial-onset seizures by a neurologist

AND

- The patient has received IV lacosamide and is not a candidate for conversion to alternate oral agent

OR

- The patient is stable on lacosamide therapy when care is transitioned to VA

OR

- The patient has had an inadequate response, intolerable side effect, or contraindication to one formulary antiepileptic medications for partial seizures, such as : carbamazepine, lamotrigine, levetiracetam, oxcarbazepine, , topiramate, and zonisamide.

For women of childbearing potential

Lacosamide is Category C. Adverse events were observed in animal reproduction studies. Available information related to use in pregnancy is limited; if inadvertent exposure occurs during pregnancy, close monitoring of the mother and fetus/newborn is recommended. A registry is available for women exposed to lacosamide during pregnancy.

Use lacosamide with caution in patients with known cardiac conduction problems or with severe cardiac disease

Dosage and Administration

Monotherapy

100 mg BID initially with increased dose at weekly intervals by 50 mg BID; up to a recommended dose of 150-200 mg BID

Alternate loading dose schedule: 200 mg as a single dose, followed ~12 hr later by starting 100 mg BID x 1 week, with increased dose at weekly intervals by 50 mg BID; up to a recommended dose of 150-200 mg BID

In patients already taking an antiepileptic drug (AED), maintain lacosamide at recommended maintenance dose of 150-200 mg PO BID for at least 3 days before initiating withdrawal of the previous AED.

Adjunctive therapy

Initial: 50 mg every BID with increased dose at weekly intervals by 50 mg BID; up to a recommended dose of 100-200 mg BID

Renal impairment

Severe (CrCl <30 mL/min): Not to exceed 300 mg/day

Hemodialysis: Supplement with up to 50% of dose after dialysis

.

Hepatic impairment

Mild to moderate: Not to exceed 300 mg/day

Severe: Not recommended

Issues for Consideration

- Antiepileptic drugs (AEDs), including lacosamide, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Monitor patients treated with any AED for any indication for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior
- Dose-dependent prolongations in PR interval with lacosamide have been observed in clinical studies in patients and in healthy volunteers
- Both atrial fibrillation and atrial flutter have been reported in open label epilepsy trials of lacosamide and in postmarketing experience.
- Lacosamide oral solution contains aspartame, a source of phenylalanine. A dose of lacosamide 200 mg oral solution (equivalent to 20 mL) contains phenylalanine 0.32 mg.
- When comparing response rates and seizure frequency, in most studies both 400mg/day and 600mg/day doses had similar outcomes with more documented adverse events at the higher dose.

Prepared: March 2016. Contact: Kathryn Tortorice Pharm D, BCPS, VA Pharmacy Benefits Management Services